

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

MUTUAL PHARMACEUTICAL  
COMPANY, INC., et al.,

Plaintiffs,

-v-

WATSON PHARMACEUTICALS, INC., et al.,

Defendants.

Civil Action No. 3:09-cv-5421 (GEB) (TJB)

**Date Returnable: August 16, 2010**

**Filed Electronically**

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**DEFENDANT WEST-WARD PHARMACEUTICAL CORP.'S MEMORANDUM OF  
LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

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## PRELIMINARY STATEMENT<sup>1</sup>

Plaintiffs claims fail for one simple reason: they engaged in precisely the same conduct that they now decry as deceptive, unsafe, and illegal. Specifically, from 1993 until at least July 2006, Plaintiff Mutual Pharmaceutical Company, Inc. (“Mutual”) sold 0.6 mg colchicine tablets in direct competition with the Defendants in this lawsuit, including West-Ward Pharmaceutical Corp. (“West-Ward”).<sup>2</sup> (SOF ¶¶ 12, 16.) Each of the over 100,000,000 colchicine tablets sold by Mutual during this time lacked FDA approval. (*Id.* ¶ 12.) While Mutual reportedly ceased distributing unapproved colchicine tablets in 2006, Mutual’s unapproved colchicine tablets remained on the market until at least 2009. (*Id.* ¶ 21.) Just *months* before it filed the present action, Mutual’s unapproved colchicine tablets appeared on at least a few of the same Price Lists and Wholesaler Ordering Systems that Plaintiffs identify by name in their Complaint. (*Id.* ¶ 22.) Indeed, Mutual’s unapproved colchicine tablets still appear on at least one of the major Price Lists referenced in the Complaint. (*Id.* ¶ 23.)

It cannot be disputed that Mutual’s unapproved colchicine tablets were marketed in a substantially identical fashion to West-Ward’s. Mutual admits that, “at a minimum, the product name, drug strength, product size, and pricing information for Plaintiffs’ [unapproved] colchicine product appeared on Price Lists [and Wholesaler Ordering Systems].” (SOF ¶ 14.) This is the precise information that currently appears on Price Lists and Wholesaler Ordering Systems with

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<sup>1</sup> The evidentiary support for the facts described herein, in addition to other relevant facts that do not appear in this brief, is set forth in West-Ward’s contemporaneously filed Statement of Undisputed Material Facts in Support of its Motion for Summary Judgment (referred to herein as “SOF”).

<sup>2</sup> Mutual Pharmaceutical Company, Inc., in conjunction with United Research Laboratories, Inc., marketed and distributed unapproved colchicine tablets from 1993 until at least 2006. (SOF ¶¶ 10, 12.) The other Plaintiffs in this lawsuit, AR Holding Company, Inc. and AR Scientific Company, Inc., are affiliates of Mutual that were formed in 2005. (SOF ¶ .) All three Plaintiffs, in addition to United Research Laboratories, Inc., are subsidiaries of URL Pharma, Inc. (*Id.* ¶¶ 10, 26.)

respect to West-Ward's colchicine tablets. (*Id.*) This is also the identical information that Plaintiffs now contend is "illegal," "unlawful," "obsolete," "false," "misleading," and "will confuse and mislead physicians, pharmacists, buyers, patients and others" in violation of the Lanham Act. (*Id.* ¶ 11; *see generally*, Pls.' Compl.)

In other words, Mutual contends that the same conduct in which it engaged for more than a decade – the listing of 0.6 mg unapproved colchicine tablets on Price Lists and Wholesaler Ordering Systems – now suddenly causes confusion in the marketplace and constitutes unlawful behavior entitling Plaintiffs to an injunction and millions of dollars in damages.

Plaintiffs have been on notice of West-Ward's unclean hands defense since the early stages of this case. The California District Court that denied Plaintiffs' Motion for Preliminary Injunction prior to the transfer to this District was skeptical of Plaintiffs' claims, concluding that, "almost up to the moment they commenced this action, they were engaged in precisely the same activity over which they now seek to enjoin their competitors . . ." and holding that "the doctrine of unclean hands substantially decreases the likelihood that Plaintiffs will ultimately prevail on the merits." *Mutual Pharm. Co., Inc. v. Watson Pharms., Inc.*, No. CV 09-5700 (PA), 2009 WL 3401117, \*4-5 (C.D. Cal. Oct. 19, 2009).

West-Ward respectfully submits that summary judgment should be granted against Plaintiffs on the basis of their unclean hands. No further discovery is necessary to resolve the issues relevant to this summary judgment motion, and the resolution of this case at this stage will spare the parties and the Court unnecessary time, resources, and substantial litigation expenses related to this case.<sup>3</sup> Plaintiffs readily admit that they engaged in the same conduct that they now

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<sup>3</sup> Assuming *arguendo* that it is not successful with this Motion, West-Ward believes that, upon the conclusion of discovery, Plaintiffs' claims will be susceptible to resolution on other grounds under Rule 56. West-Ward files this specific motion at this juncture because it focuses

contend is unlawful. (SOF ¶¶ 12-14.) There is little doubt that Plaintiffs benefited from their conduct and contributed equally to any alleged “confusion” in the marketplace. Therefore, as demonstrated below, even if Plaintiffs could somehow prove that the listing of West-Ward’s colchicine tablets on Wholesaler Ordering Systems and Price Lists confuses consumers, which is specious at best, Plaintiffs’ substantially identical conduct bars their claims as a matter of law.

### STATEMENT OF FACTS

**A. West-Ward Has Sold Colchicine Tablets for Nearly 40 Years, and the FDA Has Never Intervened to Take West-Ward’s Tablets off the Market.**

Colchicine in its isolated form has been utilized to treat and prevent gout since the late 1800s. (“SOF” ¶ 1.) West-Ward has distributed colchicine tablets in the United States since 1972. (*Id.* ¶ 2.) West-Ward estimates that it has sold more than a billion colchicine tablets since that time, with the FDA’s knowledge and acquiescence. (*Id.* ¶¶ 2-4.) The FDA has included West-Ward’s colchicine tablets on its National Drug Code Directory for more than 30 years. (*Id.* ¶ 3.) The FDA has inspected the site where West-Ward’s colchicine tablets are manufactured on at least 27 occasions since 1995 and, despite being aware of the existence of West-Ward’s colchicine tablets, the FDA has never taken any enforcement action against West-Ward’s sales or marketing of such tablets. (*Id.* ¶¶ 3, 4.) Specifically, West-Ward has never received a Warning Letter or other communication from the FDA telling West-Ward to stop manufacturing, marketing, or distributing its colchicine tablets. (*Id.* ¶ 4.)

Admittedly, West-Ward’s colchicine tablets have appeared on various Wholesaler Ordering Systems and Price Lists, as those terms are defined in Plaintiffs’ Complaint. (SOF ¶ 6.)

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on Plaintiffs’ conduct and, consequently, no additional discovery is needed to resolve this Motion. Accordingly, West-Ward respectfully reserves the right to file an additional summary judgment motion following the conclusion of discovery, assuming such motion is necessary and appropriate.

Generally, the only information about West-Ward's colchicine tablets appearing on the Price Lists and Wholesaler Ordering Systems is the product name, strength, size, National Drug Code, and price. (*Id.* ¶ 7.) Occasionally, an Orange Book Rating or Therapeutic Equivancy Rating of "N/A" or "NR" (meaning "not applicable" or "Not Rated") appears on the aforementioned databases.<sup>4</sup> (*Id.* ¶ 8.) To West-Ward's knowledge, no Price List or Wholesaler Ordering System has ever designated West-Ward's colchicine tablets as "FDA approved," or the like. (*Id.* ¶ 9.)

**B. Plaintiffs Sold and Marketed Unapproved Colchicine Tablets in the Same Manner as West-Ward.**

Mutual is a subsidiary of URL Pharma, Inc. and an affiliate of United Research Laboratories, Inc.<sup>5</sup> (SOF ¶ 10.) Mutual sold and distributed more than 100,000,000 0.6 mg colchicine tablets without FDA approval from 1993 until July 2006 in direct competition with the Defendants in this lawsuit. The colchicine tablets that Mutual sold were manufactured by West-Ward and Defendant Excellium Pharmaceutical, Inc. ("Excellium"), and were accompanied by the same prescribing information that accompanied West-Ward's and Excellium's products. (*Id.* ¶¶ 12, 16.) During that time period, Mutual's unapproved 0.6 mg colchicine tablets were priced at approximately \$0.09 per tablet. (*Id.* ¶ 17.) In July 2006, Mutual reportedly ceased its distribution of unapproved colchicine tablets, but pharmacies and wholesalers continued to sell Mutual's unapproved colchicine tablets for several more years, using the Price Lists and Wholesaler Ordering Systems and, thereby, perpetuating Mutual's "advertising," if indeed these actions constitute "advertising." (*Id.* ¶¶ 21-23.)

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<sup>4</sup> As set forth in the Declaration of Michael Raya in Support of this Motion at ¶ 12, "N/A" and "NR" mean "not applicable" or "not rated."

<sup>5</sup> As used in this Motion, the term "Mutual" shall mean Mutual Pharmaceutical Company, Inc., URL Pharma, Inc., and United Research Laboratories (a/k/a URL).

Importantly, Mutual's unapproved colchicine tablets *still* appear on at least one of the major Price Lists – Medi-Span – with an “NR” rating. (SOF ¶ 23.) Mutual's unapproved colchicine tablets also appeared on several of the other Wholesaler Ordering Systems and Price Lists until at least March 2009 – just months before Plaintiffs filed this lawsuit. (*Id.* ¶ 22.) Mutual admittedly provided the following information about its unapproved colchicine tablets to the Wholesaler Ordering Systems and Price Lists: product name, strength, size, a copy of its unapproved label and package insert, along with the National Drug Code and pricing. (*Id.* ¶ 14.) Mutual also affirmatively represented to Wholesalers and Price Lists that its unapproved colchicine tablets had an “NR” rating. (*Id.* ¶ 19.) Notably, as recently as November 13, 2006, Mutual expressly advertised its unapproved colchicine tablets on its company website as having a “Rating” of “NR.” (*Id.* ¶ 20.)

**C. Plaintiffs' Recent Efforts to Monopolize the Colchicine Market.**

Plaintiffs submitted to the FDA a New Drug Application (“NDA”) for their 0.6 mg colchicine tablets for the treatment of gout flares on or about September 30, 2008. (SOF ¶ 29.) Immediately after submitting their NDA to the FDA – and well prior to obtaining the FDA's approval – Plaintiffs began lobbying the FDA to take action against distributors of unapproved colchicine tablets, including West-Ward. (*Id.* ¶ 30.)

Plaintiffs have correctly acknowledged that “[o]nly the FDA has the authority to remove unapproved colchicine from the market.” (*Id.* ¶ 32.) Nevertheless, Plaintiffs asserted in their marketing literature that, in the event that the FDA delays in taking enforcement action against unapproved colchicine, Plaintiffs “have a proven legal strategy to take the unapproved off the market in rapid fashion.” (SOF ¶ 33.) The purported blue print for Plaintiffs' perceived “proven legal strategy” was developed a few years earlier. (*Id.* ¶¶ 27-28.)

Specifically, in 2006, Plaintiffs obtained FDA approval for quinine sulfate, a well-established drug for the treatment of malaria that had been sold for years without FDA approval. (SOF ¶ 27.) When the FDA did not take immediate action against the sale of unapproved quinine sulfate following Plaintiffs' approval, Plaintiffs filed a lawsuit in the Central District of California, asserting, *inter alia*, claims of unfair competition and false advertising against the distributors of unapproved quinine sulfate. (*Id.*; see *Mutual Pharm. Co., Inc. v. Ivax Pharm., Inc.*, 459 F. Supp. 2d 925 (C.D. Cal. 2006) (hereinafter, "*Ivax*"). The *Ivax* Court granted Plaintiffs' motion for preliminary injunction, at the same time noting that the FDA's primary jurisdiction over the dispute was "the only argument raised by defendants as to why Mutual lacks a probability of success on this claim." (SOF ¶ 28.) The parties eventually settled that case.

In anticipation of bringing a similar action against the manufacturers and distributors of colchicine tablets, Plaintiffs began seeking the removal of their unapproved colchicine tablets from Price Lists and Wholesaler Ordering Systems in February and March of 2009. (SOF ¶ 22.) Several months later, on July 29, 2009, Plaintiffs obtained FDA approval for their colchicine tablets and immediately began marketing their product at a price of \$4.85 per tablet – an approximately **5000%** increase in price from the \$.09 colchicine tablets that Mutual sold only a few years earlier. (*Id.* ¶ 34.) The public backlash from Plaintiffs' attempt to monopolize the colchicine market has been well documented, and much of this public displeasure has been shared with the FDA. (*Id.* ¶ 36.)

**D. To Date, the FDA Has Taken No Action to Remove West-Ward's Colchicine Tablets From the Market.**

In the wake of this public criticism and the unexpected price increase to consumers, the FDA has not taken any enforcement action against West-Ward's colchicine tablets. (SOF ¶ 37.) This delay in action by the FDA is consistent with its published and clearly defined policies. (*Id.*

¶¶ 38-41.) In particular, in 2008, the FDA took formal enforcement action against the *injectable* form of colchicine, removing it from the market entirely. (*Id.* ¶ 39.) In the corresponding Federal Register notice, the FDA expressly noted that the *oral* form of colchicine is substantially safer than the *injectable* form, stressing that “[t]his notice does not affect the legal status of products containing colchicine in oral dosage forms, which FDA intends to address at a later date.” (*Id.*) The FDA has similarly posted on its website that “FDA is not taking any orally administered colchicine products off the market at this time, whether approved or unapproved.” (*Id.* ¶ 40.)

In addition, the FDA emphasizes in its Marketed Unapproved Drugs -- Compliance Policy Guide, which was published by the FDA in 2006 to deal with this situation, that when another company obtains approval to market a product that other companies were previously marketing without approval, the FDA will normally allow a grace period before it takes any action against the unapproved products. (SOF ¶ 41.) The FDA also emphasizes in the Compliance Policy Guide that “[t]he length of any grace period and the nature of any enforcement action taken by FDA will be decided on a case-by-case basis . . . .” (*Id.*)<sup>6</sup>

#### **E. Plaintiffs Filed the Present Lawsuit Against West-Ward in August 2009.**

Following the FDA’s approval of their colchicine tablets, Plaintiffs again began pressing the FDA to take immediate enforcement action against unapproved colchicine tablets. (SOF ¶ 42.) To date, the FDA appears to have declined these requests, except as against Defendant Vision Pharma, LLC (“Vision”) and its manufacturer, as detailed in footnote six herein. (SOF ¶ 51, 52.) Rather than wait for the FDA to take action against all distributors of unapproved

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<sup>6</sup> On April 29, 2010, FDA issued a warning letter to Defendant Vision against its continued distribution of colchicine tablets. That letter accused Vision of selling an unapproved new drug, but it followed a warning letter sent a few months earlier to Vision’s manufacturer, Sunrise Pharmaceutical, Inc., in which FDA found Sunrise guilty of numerous GMP (good manufacturing practices) violations. (SOF ¶ 52.)

colchicine, Plaintiffs initiated their backup “legal strategy,” seeking relief from the United States District Court for the Central District of California, the same district in which Plaintiffs obtained a preliminary injunction in the *Ivax* case. (*Id.* ¶ 43.)

In their lawsuit, Plaintiffs allege that the appearance of Defendants’ unapproved colchicine tablets on Wholesaler Ordering Systems and Price Lists “constitute[s] false and misleading descriptions or representations of fact that their colchicine products are safe, effective and/or FDA approved, and that the safety and warning information provided with Defendants’ unapproved colchicine products is complete.” (Pls.’ Compl. [Doc. No. 1] ¶ 143.) In particular, Plaintiffs allege in their Complaint that “relevant consumers are likely to mistakenly believe that the ‘NR’ or ‘N/A’ rating means that their unapproved colchicine products do not need to be approved by the FDA in order to be sold lawfully.” (*Id.* ¶¶ 111-112.)

Plaintiffs also allege that “Defendants’ labels fail to mention many of the drug-drug interactions, food interactions and contraindications required by the FDA on Mutual’s approved label,” and that these “practices irreparably damage Plaintiffs because they will confuse and mislead physicians, pharmacists, buyers, patients and others into falsely believing that Plaintiffs’ COLCRYS product is dangerous, unsafe and fraught with risk compared to Defendants’ misleadingly and deceptively labeled products.” (*Id.* ¶¶ 125, 137.)

Plaintiffs filed a Motion for Preliminary Injunction against Defendants on September 11, 2009, seeking to enjoin Defendants from marketing, selling, and/or distributing their colchicine tablets. (SOF ¶ 44; *see also* Pls.’ Notice of Mot. And Mot. For Prelim. Inj. [Doc. No. 50].) Defendants defended Plaintiffs’ Motion for Preliminary Injunction on the merits, something that the defendants in the *Ivax* case elected not to do. (SOF ¶ 45; *see also* Order dated October 19, 2009 [Doc. No. 139] (holding that “[h]ere, however, Defendants have not just relied on the

primary jurisdiction doctrine. They also attack the merits of Plaintiffs’ false advertising claim, the sufficiency of the evidence presented by Plaintiffs, and the equities of enjoining Defendants from engaging in the very same behavior that Plaintiffs were also engaged in until days before they commenced this litigation.”.)

The California Court entered an Order denying Mutual’s Motion for Preliminary Injunction on October 19, 2009, holding, *inter alia*, that:

- “[T]his Court is reluctant to view the Lanham Act’s false advertising provisions as broadly as did the Ivax court.”
- “[T]he Court is not convinced that having drugs listed on a Price List or drug ordering system maintained by a third party even constitutes a ‘false statement’ in ‘commercial advertising or promotion’ to fall within the scope of the Lanham Act’s false advertising provisions.”
- “Moreover, there is little evidence that Defendants have in any way created the confusion experienced by pharmacists, or that this confusion is limited to colchicine products.”
- “Plaintiffs’ contentions concerning the product labels and inserts are even weaker, both because the evidence of confusion is weaker and because disputes concerning the content of those labels and inserts falls even more squarely within the primary jurisdiction of the FDA.”

(SOF ¶ 45; Order dated October 19, 2009 [Doc. No. 139].)

Importantly, the Court also noted that “the evidence indicates that almost up to the moment they commenced this action, [Plaintiffs] were engaged in precisely the same activity over which they now seek to enjoin their competitors.” (SOF ¶ 47; Order dated October 19,

2009 [Doc. No. 139].) The transferor Court, therefore, concluded that “the doctrine of unclean hands substantially decreases the likelihood that Plaintiffs will ultimately prevail on the merits.” (*Id.*) In addition, that Court transferred the lawsuit to this District. (SOF ¶ 48; Order dated October 19, 2009 [Doc. No. 139].)

In the days, weeks, and months after Plaintiffs’ Motion for Preliminary Injunction was denied, Plaintiffs sent additional letters to the FDA, again urging the agency to take immediate enforcement action against unapproved colchicine tablets. (SOF ¶ 50.) To date, the FDA has taken no action against West-Ward. (*Id.* ¶ 51.)

## ARGUMENT AND CITATION TO AUTHORITY

### I. Summary Judgment Standard

Summary judgment should be rendered if “the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Orson, Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1366 (3d Cir. 1996); *Hersh v. Allen Prods. Co.*, 789 F.2d 230, 232 (3d Cir. 1986).

Rule 56(e) of the Federal Rules of Civil Procedure provides, in relevant part:

When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party.

FED. R. CIV. P. 56(e). “Under the Rule, a movant must be awarded summary judgment on all properly supported issues identified in its motion, except those for which the nonmoving party has provided evidence to show that a question of material fact remains.” *Slaughter v. Rogers*, No. 07-2163 (GEB), 2010 WL 2539841, at \*2 (D.N.J. June 17, 2010) (citing *Celotex*, 477 U.S. at

324). Specifically, the nonmoving party “must do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (citations omitted); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (stating that “[b]y its very terms, this standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of material fact.”).

## **II. Plaintiffs’ Unclean Hands Bar Their Claims.**

Federal courts have widely utilized the unclean hands doctrine to deny relief to plaintiffs in Lanham Act false advertising cases. The United States Supreme Court long ago warned that “it is essential that the plaintiff should not in his trade mark, or in his advertisements or business, be himself guilty of any false or misleading representation.” *Worden v. Cal. Fig Syrup Co.*, 187 U.S. 516, 528 (1903). Relief sought pursuant to the Lanham Act, including a request for monetary damages, is “subject to the principles of equity.” 15 U.S.C. § 1117(a). The “unclean hands” doctrine “closes the doors of a court of equity to one tainted with inequity or bad faith relative to the matter in which he seeks relief.” *Precision Instr. Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945). To apply the unclean hands doctrine, the movant must prove that “some unconscionable act of one coming for relief has *immediate and necessary relation* to the equity that he seeks in respect of the matter in litigation.” *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933) (emphasis supplied).

In the present case, the acts that Plaintiffs allege to be “unlawful,” “illegal,” “false” and “misleading” have an *immediate and necessary relation* to Plaintiffs’ conduct. To be clear, the alleged acts are precisely the same acts that Plaintiffs engaged in – and benefited from – for at

least thirteen (13) years. To the extent that Defendants' conduct causes confusion in the marketplace as Plaintiffs allege, Plaintiffs' role in causing such confusion is indistinguishable. As Plaintiffs readily admit and, as the Court in this case already concluded, Plaintiffs actively sold unapproved 0.6 mg colchicine tablets – in direct competition with Defendants and in the same manner as Defendants – from 1993 until 2006, with residual sales continuing for several additional years. More importantly, Plaintiffs' unapproved colchicine tablets appeared on Price Lists and Wholesaler Ordering Systems up until, and even after, the time they filed the present lawsuit. In fact, the evidence shows that Plaintiffs' unapproved colchicine tablets *still* appear on at least one of the major Price Lists. Notably, Plaintiffs' unapproved colchicine tablets were, and still are, designated with an "NR" rating on Price Lists and Wholesaler Ordering Systems, as they previously were on Plaintiffs' own website. Plaintiffs are the proverbial "pot calling the kettle black."

The story does not end there. The unapproved colchicine tablets that Plaintiffs distributed between 1993 and 2006 were manufactured by two of the Defendants in this lawsuit, West-Ward and Excellium. Those tablets were accompanied by the exact same prescribing information contained in bottles of West-Ward's and Excellium's colchicine tablets. This is the same prescribing information that Plaintiffs now contend "pose[s] a serious risk to the public," and "confuse[s] and mislead[s] physicians, pharmacists, buyers, patients and others." (*See* Pls. Compl. [Doc. No. 1] ¶ 137.)

Courts have consistently denied relief in false advertising cases on the basis of unclean hands where the party seeking relief engaged in conduct similar to that of which it complains. For example, in *Emco, Inc. v. Obst*, No. 03-6432, 2004 WL 1737355 (C.D. Cal. July 29, 2004), DBW, a diamond blade distributor, sued competitor Mared, for false advertising because its use

of the trade name “Detroit Industrial Tools” allegedly misled consumers into believing that Mared’s blades were American made. *Id.* at \*1. Mared defended on the ground that DBW had “unclean hands” because it sold under the name “Americut” and included photos of American icons in its advertising, which similarly misled consumers into believing that its foreign-made blades were manufactured in this country. *Id.*

Affirming the applicability of the unclean hands defense, the court began by noting that in order to state a false advertising claim, “[i]t is essential that the plaintiff should not ... be himself guilty of any false or misleading representation ....” *Id.* at \*4 (quoting *Worden v. Cal. Fig Syrup Co.*, 187 U.S. 516, 528 (1903)). Concluding that DBW’s conduct directly related to the subject matter of its complaint, the court granted summary judgment to Mared on DBW’s false advertising claims. *Id.* at \*6.

Similarly, the court in *Rainbow Play Systems, Inc. v. Backyard Adventure, Inc.*, No. 06-4166, 2009 WL 3150984 (D.S.D. Sept. 28, 2009) granted summary judgment in a false advertising case on the basis of unclean hands, concluding that “[i]f Defendants have engaged in inequitable conduct by referring to lumber from a tree that is not classified as cedar in a scientific or botanical classification, Rainbow has also engaged in inequitable conduct.” *Id.* at \*6 (noting that “[a]lso, Rainbow’s conduct of referencing its lumber as cedar clearly has a material relation to the equitable relief that the plaintiff seeks.”). Importantly, the Court also emphasized that it did “not find persuasive Rainbow’s arguments that it was more justified in referring to its lumber as cedar.” *Id.*; see also *Haagen-Dazs, Inc. v. Frusen Gladje Ltd.*, 493 F. Supp. 73, 76 (S.D.N.Y. 1980) (grounding a denial of a preliminary injunction on unclean hands even though “defendants’ hand may be a shade or two less clean”).

Under the present facts, Plaintiffs' belated effort, a few months before filing suit, to remove their unapproved colchicine products from some of the Price Lists and Wholesaler Ordering Systems does not alter West-Ward's entitlement to summary judgment. Again, for at least 13 years, Plaintiffs' conduct was virtually identical to that of which they now complain and Plaintiffs' unapproved colchicine tablets still remain on at least one of the major Price Lists. Plaintiffs also profited for years from their conduct. To the extent any confusion exists in the marketplace regarding the FDA's stance on colchicine, Plaintiffs' role in such confusion cannot be distinguished from that of Defendants.

Under these circumstances, the law does not permit Plaintiffs to seek relief pursuant to the Lanham Act simply because such relief would suddenly benefit Plaintiffs. *See Proctor & Gamble Co. v. Ultreo*, 574 F. Supp. 2d 339, 355 (S.D.N.Y. 2008) (concluding that the unclean hands doctrine barred the relief sought by plaintiff where "at a time when P & G's commercial interests were different, P & G made the very same claims that it now attacks as false, and relied on the very science it now claims is inadequate."); *Stokely-Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 534 (S.D.N.Y. 2009) (denying the relief sought pursuant to plaintiff's false advertising claim on the ground that plaintiff previously engaged in the same conduct of which it complained, concluding that "SVC cannot, having jumped on the bandwagon of calcium and magnesium first, now jump off and claim that Coca-Cola must get off too."); *Salomon Smith Barney, Inc. v. Vockel*, 137 F. Supp. 2d 599, 603 (E.D. Pa. 2000) (denying relief on the basis of unclean hands, stating: "Smith Barney seeks the help of a court of equity to prevent the same conduct by Vockel which it had previously abetted and from which it has handsomely profited," and concluding that "[i]f what Vockel is doing in 2000 is wrong, it is hard to see why Vockel's and Smith Barney's conduct in 1994 was not wrong."); *West v. West*, 825 F. Supp. 1033, 1050

(N.D. Ga. 1992) (dismissing plaintiff's claim where he "comes into court, seeking to stop essentially the same types of transactions from which he once benefited," and holding that "[t]he unclean hands doctrine was established to prevent just this type of scenario.")

Because it is indisputable that Plaintiffs engaged in the precise conduct that they now allege is unlawful – listing the same unapproved 0.6 mg colchicine tablets on the same Wholesaler Ordering Systems and Price Lists as West-Ward and using the same prescribing information – West-Ward submits this Motion at this stage to save the parties and the Court from the time, labor, and expense associated with unnecessary litigation. Specifically, even if Plaintiffs can somehow prove all of the elements of a Lanham Act claim, the doctrine of unclean hands bars the relief sought by Plaintiffs. This case is, therefore, ripe for summary judgment on this issue. *See Diamond Triumph Auto Glass, Inc. v. Safelite Glass Corp.*, 441 F. Supp. 2d 695, 709 n.10 (M.D. Pa. 2006) (concluding that plaintiff "used the same greetings in the same manner for which it seeks relief," and holding that "even if Diamond could successfully establish that Safelite's greetings violated the Lanham Act, the unclean hands doctrine would require that we grant summary judgment."). Accordingly, assuming *arguendo* that Plaintiffs eventually are able to show that West-Ward's purported "advertising" has created any actionable confusion in the minds of its customers, Plaintiffs are still barred by the doctrine of unclean hands from obtaining the relief they seek. *Id.*<sup>7</sup> Summary judgment is, therefore, appropriate at this time.<sup>8</sup>

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<sup>7</sup> Of course, the transferor Court already questioned Plaintiffs' interpretation of the law on these very issues. (*See* SOF ¶ 46; Order dated Oct. 19, 2009 [Doc. No. 139].)

<sup>8</sup> West-Ward respectfully submits that summary judgment should be granted on all three of Plaintiffs' remaining claims. While the Court has left open the issue of whether California or New Jersey law applies with respect to Plaintiffs' remaining state law claims (Mem, Op. dated Feb. 10, 2010 [Doc. No. 208]), this District and courts in the Ninth Circuit (the locale of the transferor court) have consistently concluded that where a Lanham Act claim is dismissed, it is also proper to dismiss related state law unfair competition claims. *See Cleary v. News Corp.*, 30

## CONCLUSION

Based on the foregoing, West-Ward's Motion for Summary Judgment should be granted.

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F. 3d 1255, 1262-63 (9th Cir. 1994) (“[S]tate common law claims of unfair competition and actions pursuant to California Business and Professions Code § 17200 are ‘substantially congruent’ to claims made under the Lanham Act.”); *Denbicare U.S.A. Inc. v. Toy’R’Us, Inc.*, 84 F.3d 1143, 1152-53 (9th Cir. 1996) (same; holding that “since dismissal of Denbicare’s Lanham Act claim was proper, dismissal of its § 17200 [and § 17500] claim[s] was proper as well”); *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 454 (D.N.J. 2009) (“unfair competition claims under New Jersey statutory and common law generally parallel those under § 43(a) of the Lanham Act.”); *J & J Snack Foods, Corp. v. Earthgrains Co.*, 220 F. Supp. 2d 358, 374 (D.N.J. 2002) (extending the Court’s Lanham Act analysis to state law unfair competition claims and, accordingly, granting summary judgment against plaintiffs on all claims).